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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CANELLA, KAREN A

ART UNIT PAPER NUMBER

1642

DATE MAILED: 12/04/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/765,060

Applicant(s)  
Yu

Examiner  
Karen Canella

Art Unit  
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 30 days MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-79 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-9, drawn to a combination comprising an oxidizing or reducing agent, a protein denaturing agent and a hapten, kits thereof, classified in class 424, subclass 278.1.
  - II. Claim 78, in part, drawn to the combination of Group I further comprising a suicide gene sequence or a cytolytic gene sequence, classified in class 424, subclass 278.1 and class 514, subclass 44.
  - III. Claim 78, in part, drawn to the combination of Group I further comprising a cytokine gene sequence or a cytokine containing depot, classified in class 424, subclasses 85.1 and 278.1, and class 514, subclass 44 and 885.
  - IV. Claim 78, in part, drawn to the combination of Group I further comprising a reporter and a reporter gene sequence, classified in class 424, subclass 278.1 and class 514, subclass 44.
  - V. Claim 78 in part, drawn to the combination of Group I further comprising a radiation sensitizer, classified in class 424, subclass 278.1 and, for example, class 514, subclass 212.
  - VI. Claims 25-28, drawn to the combination of Group I, further comprising immune potentiators, classified in class 424, subclasses 1.11 and 278.1.
  - VII. Claims 10-13, drawn to the combination of Group I, further comprising anti-angiogenic compounds, classified in class 424, subclass 278.1 and for example, class 514, subclass 21. Claim 10 will be examined with this group to the extent that it reads on a combination comprising an anti-angiogenic agent.

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- VIII. Claims 10, 14, 57 and 61, drawn to the combination of Group I, further comprising chemotherapeutic compounds and a method of using this combination in the treatment of neoplasms, classified in class 424, subclass 278.1 and for example, class 514, subclass 34. Claims 10 and 57 will be examined with this group to the extent that it reads on a combination comprising a chemotherapeutic agent.
- IX. Claims 10, 15-20, drawn to the combination of Group I, further comprising tumor suppressors and oncogene inhibitors, classified in class 424, subclass 278.1, class 424, subclasses 130.1 and 138.1, and class 514, subclass 44.
- X. Claims 36-38, 49-56, 68, 69, 72-77, drawn to a method for treating a neoplasm in a mammal comprising administering a hapten and a coagulation agent and a method for treating a mammal comprising administering a the combination of group I, classified in class 424, subclass 278.1 and class 530, subclasses 381-384 and 834. Claim 36 will be examined with this group to the extent that it reads on coagulation agents, as opposed to coagulation therapies.
- XI. Claims 47 and 48, drawn to a method for treating a neoplasm in a mammal comprising administering a hapten, a coagulation agent and a coagulation lysing agent, classified in class 424, subclass 278.1, class 424, subclass 94.1 and 94.21, and class 530, subclasses 381-384 and 834.
- XII. Claims 39-42, drawn to a method for treating a neoplasm comprising the administration of a hapten, a coagulation agent, and a facilitating agent to conjugate the hapten to a tumor antigen, classified in class 424, subclass 278.1 class 530, subclasses 403 and 807, and class 530, subclasses 381-384 and 834.
- XIII. Claims 43-46, drawn to a method for treating a neoplasm comprising the administration of a hapten, a coagulation agent, and an immune response

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potentiator, classified in class 424, subclasses 1.1 and 278.1, and class 530, subclasses 381-384 and 834..

- XIV. Claims 57, and 62-67, drawn to ,a method for treating a neoplasm in a mammal comprising administering the combination of group IX classified in class 514, subclass 44 and class 530, subclasses 387.1 and 387.7. Claim 57 will be examined with this group to the extent that it reads on the administration of tumor suppressor genes, proteins or oncogene inhibitors.
- XV. Claims 57-60, drawn to a method for treating a neoplasm in a mammal comprising administering the combination of group VII, classified in class 424, subclass 278.1 class 530, subclass . Claim 57 will be examined with this group to the extent that it reads on the administration of anti-angiogenic agents.
- XVI. Claims 36-38 and 70-75, drawn to a method for treating a neoplasm in a mammal comprising administering a hapten and a coagulation treatment, classified in class 424, subclass 278.1 class 600, subclasses 9 and 10, and class 604, subclass 20. Claims 36-38 and 72-75 will be examined with this group to the extent that they read on a coagulation treatment as opposed to the administration of a coagulation agent.
- XVII. Claim 79, in part, drawn to a method for treating a neoplasm in a mammal comprising the administration of the combination of Group II, classified in class 424, subclass 278.1 class 514, subclass 44.
- XVIII. Claim 79, in part, drawn to a method for treating a neoplasm in a mammal comprising the administration of the combination of Group III, classified in class 424, subclass 278.1 class 514, subclass 885.
- XIX. Claim 79, in part, drawn to a method for treating a neoplasm in a mammal comprising the administration of the combination of Group IV, classified in class 424, subclass 278.1 class 514, subclass 44.

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XX. Claim 79, in part, drawn to a method for treating a neoplasm in a mammal comprising the administration of the combination of Group V, classified in class 424, subclass 278.1, and for example, class 514, subclass 212.

2. The inventions are distinct, each from the other because of the following reasons:

The Inventions of Groups I-VII and IX are structurally and functionally different products which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The methods of Groups VIII and X-XX differ in the method objectives, method steps and parameters and in the reagents used.

The products of Inventions I, II, III, IV, V, VI, IX and VII are respectively related to the methods of Inventions X, XVII, XVIII, XIX, XX, XIII, XIV and XV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case and of the products of Inventions I, II, III, IV, V, VI, IX and VII can be used in a process of raising an antibody in an experimental animal.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper.


3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.  
Patent Examiner, Group 1642  
November 19, 2001

  
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